REMARKS

Claims 16-27 were pending. Claims 1-15 and 28-49 had been previously cancelled. By this response, claims 16 and 20 have been amended, no claims have been cancelled, and claims 50-54 have been added. Support for these amendments, and for any new claims, may be found throughout the specification, but especially in paragraphs [0040]-[0052] and [0111]-[0125] and FIGS. 1A-1B. Cancellation or amendment of any claim is not to be considered a dedication to the public of any subject matter.

Thus, claims 16-27, and 50-54 are currently under consideration.

OVERALL COMMENTS

As described in the specification, the methods claimed herein are directed to methods of forming a "hyperelastic" single crystal shape memory copper aluminum alloys, and particularly to methods of forming a hyperelastic material that may be used to form a device such as a guidewire. These hyperelastic shape memory alloys are anisotropic and have significantly different properties from polycrystalline shape memory alloys, and even from other single-crystal shape memory alloys previously described, including: being deformable at a constant force at recoverable strain of at least 9%, having a very narrow loading-unloading hysteresis, having a recovery which is completely repeatable and complete, and having a very low yield strength when in the martensitic phase. These unique properties are at least partially a result of the method in which the single crystal copper aluminum alloys are prepared. These hyperelastic shape memory alloys are distinguishable from superelastic shape memory alloys, which may include both polycrystalline and single crystal shape memory alloys.

The pending claims have been amended to clarify the differences between the prior art methods of manufacturing. The prior art cited generally refers to methods of making shape memory alloys that are not appropriate for making a guidewire having hyperelastic properties. Each of the references raised by the Examiner in the Office Action of August 8, 2008 are discussed in light of the pending claims below. As discussed, the Applicants assert that these references, either alone or in combination, do not teach or suggest all of the elements recited in the pending

claims. Thus, the Applicants respectfully request withdrawal of the rejections, and allowance of the pending claims.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

Claims 16-19

Claims 16-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoichi (JP2000-185999) in view of Recarte et al. (Influence of Al and Ni concentration on the martensitic transformation in Cu-Al-Ni shape-memory alloys; Metallurgical and Materials Transactions A, Vol. 33A, August 2002, p. 2581-2591) and Kravetsky U.S. 4,915,773 as a teaching reference.

The Applicants respectfully disagree.

As amended, claim 16, from which claims 17-19 depend, recites a method of fabricating an anisotropic, single crystal shape memory alloy having hyperelastic properties for use as a guidewire, including the steps of: lowering a seed of a copper aluminum based alloy into a molten melt of a copper aluminum based alloy, *wherein the seed is aligned on the <100> crystallographic direction in a direction of pulling*, and pulling a column of the alloy *of a length greater than 42 inches* from the melt by pulling a column of the alloy *of a length greater than 42 inches* from the melt by pulling at a predetermined pulling rate *so that the rising column is cooled relative to the melt, to form a crystallization front above the surface of the melt,* wherein the melt has a composition so that the pulled single crystal column has a transition temperature from martensite to austenite that is below 37 degrees Celsius.

None of the references (Yoichi, Recarte et al, or Kravetsky) teach or suggest these steps.

For example, Yoichi teaches a method for manufacturing alloy monocrystals "at a processing rate of 30% or more" requiring holding the alloy formed at a temperature within 50°C of the melting point (Yoichi translation, pages 2, and 4-5). This method involves melting by high frequency heating and casting in molds to form round rods of material that were then cold-processed into wires that are held at a temperature of 1050°C for 10 hours before quenching.

Although Yoichi is directed to one method of forming monocrystals of shape memory alloy material, Yoichi does not teach any of the steps recited by claim 16 (even prior to the amendments

made by this response). The Office Action of 8/8/08 incorrectly states that Yoichi teaches "a mixture of Cu, Al, and M... pulled to form a single crystal by a method such as the Bridgman method or other means..." (Office Action of 8/8/08, page 3). Yoichi teaches only a method of casting that is explicitly not a pulling method such as Bridgman. In fact, Yoichi teaches way from pulling methods such as Brigman. See Yoichi translation, page 3 ("Obtaining monocrystals from Cu-Al-M melts by measures such as the Bridgeman [sic] method is technically possible. But from the standpoint of practical use of Cu-Al-M alloys, monocrystallization by these measures is very expensive and is unrealistic. Moreover, when growing multi-component alloy monocrystals from melts, a concomitant problem of segregation occurs in many cases.").

Furthermore, neither Recarte nor Kravetsky can cure the deficiencies of Yoichi.

Applicants agree with the Office Action's characterization that Recarte is a study of the effect of AL and Ni concentration on the martensitic transformation temperature of Cu-Al-Ni alloys, including single-crystal alloys fabricated by "the Czochralski-Stepanov method." However, although Recarte mentions one method of fabricating single-crystals of Cu-Al-Ni, it does not teach or even suggest the method claimed by the Applicants. As mentioned, the claimed method recites a method of forming a single-crystal Cu-AL-Ni material that will exhibit *hyperelastic* properties and includes the steps of: lowering a seed of a copper aluminum based alloy into a molten melt of a copper aluminum based alloy, *wherein the seed is aligned on the <100> crystallographic direction in a direction of pulling*, and pulling a column of the alloy *of a length greater than 42 inches* from the melt by pulling at a predetermined pulling rate so that the rising column is cooled relative to the melt, *to form a crystallization front above the surface of the melt*, wherein the melt has a composition so that the pulled single crystal column has a transition temperature from martensite to austenite that is below 37 degrees Celsius.

Applicants do not dispute that single crystals of Cu-Al-Ni were in the prior art; however, Applicants assert that the methods of fabricating an anisotropic, single crystal shape memory alloy having hyperelastic properties for use as a guidewire were not previously known. In particular, methods such as the Czochralski-Stepanov method are not suitable for the fabrication of guidewires (e.g., lengths of material greater than 42 inches) having hyperelastic properties.

Similarly, Kravetsky does not cure the deficiencies of Yoichi and Recarte. Kravetsky teaches a process for growing shaped single crystals of "refractory optically transparent metal

compounds." The Kravetsky process is incompatible with the Applicants' claimed methods. For example, Kravestsky teaches away from rapidly quenching the single crystal formed. According to Kravetsky, the crystals formed by the method taught must be slowly cooled to prevent cracking and damage:

> "After growing the single crystal ... the single crystal is cooled to a temperature of 1,550° to 1,600°C at a rate of 20°-30°C/min by way of decreasing the power of the heater 7... If upon cooling of the single crystal 3 the rate of temperature lowering is above 30°C/min or the lower limit of temperature decrease is above 1,600°C., cracking may occur, as experience shows, at the end of the single crystal 3 owing to a considerable value of thermoelastic stresses. In this region of the single crystal 3 cracks and chips may appear as well. The yield of suitable single crystals is thereby reduced. The service life of such single crystals is also shortened....
>
> After lowering the temperature to 1,550°C the heater 7 is switched-off and a further cooling of the single crystal 7 is effected in a natural way to the ambient temperature." (Kravetsky, col. 6, lines 16-42).

As described in the specification, rapid quenching, as claimed, is important in maintaining the hyperelastic properties of the material formed, particularly to prevent selective precipitation of individual elemental components. Moreover, Kravetsky teaches away from maintaining them melt at a constant temperature. Kravetsky's method of forming optically transparent crystals requires that the temperature of the melt be varied as part of the processing (see, e.g., Kravetsky col. 5, line 15 to col. 6, line 15).

Thus, none of Yoichi, Recarte, or Kravetsky, either alone or in combination, teaches or even suggests the method recited in the Applicants' pending claims. Therefore claims 16-19 cannot be obvious under the combination of Yoichi, Recarte and Kravetsky. The Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 16-19 for at least the reasons given above.

<u>Claims 20, 21, 23, 24, 26, and 27</u>

Claims 20, 21, 23, 24, 26, and 27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoichi in view of Recarte et al. and Kravetsky as applied to claims 16-19 above, in further view of Solar U.S. 6,042,553.

As described above, none of Yoichi, Recarte, nor Kravetsky, either alone or in combination, teach or even suggest the steps of the independent claim 16, from which claims 20, 21, 23, 24, 26 and 27 depend. Furthermore, Solar cannot cure this deficiency.

Solar describes a processing method involving twisting an elongate metal alloy to reduce torsional elasticity while maintaining longitudinal elasticity. Solar does not teach any of the method steps of claim16, from which claims 20, 21, 23, 24, 26 and 27 depend.

Thus, Yoichi, Recarte, Kravetsky, and Solar, either alone or in combination, do not teach or even suggest the method recited in the Applicants' pending claims. Therefore claims 20, 21, 23, 24, 26, and 27 cannot be obvious under the combination of Yoichi, Recarte, Kravetsky and Solar. The Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 20, 21, 23, 24, 26, and 27 for at least the reasons given above.

Claims 22 and 25

Claims 22 and 25 stand ejected under 35 U.S.C. §103(a) as being unpatentable over Yoichi in view of Recarte et al., Kravetsky, and Solar U.S. 6,042,553 as applied to claims 20, 21, 23, 24, 26, and 27 above, and in further view of Pai U.S. 2003/0078465.

Pai teaches surgical tensioning structures that are implanted to recondition vascular tissue. Pai does not describe single-crystal shape memory alloys or methods of fabricating them, and cannot cure any of the deficiencies of the Yoichi, Recarte, Kravetsky or Solar patents described above in reference to claims 16 and 20, from which claims 22 and 25 depend. Thus, these claims cannot be found obvious by the combination of Yoichi, Recarte, Kravetsky, Solar and Pai. The Applicants respectfully request withdrawal of the 35 U.S.C. §103(a) rejection of claims 22 and 25, for at least the reasons discussed above.

DOUBLE PATENTING REJECTIONS

Claims 16, 17, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20 and 21 of copending U.S. Patent Application No. 11/948,852.

Applicants respectfully disagree. Claims 16, 17 and 19 (as amended) are patentably distinct from claims 20 and 21 of co-pending U.S. Patent Application No. 11/948,852. In particular, claims 16, 17 and 19 recite steps not included in claims 20 and 21 of co-pending U.S. Patent Application No. 11/948,852, and which are not obvious variations of claims 20 and 21. For example, claims 16, 17 and 19 recite the steps of lowering a seed of a copper aluminum based alloy into a molten melt of a copper aluminum based alloy, wherein the seed is aligned on the <100> crystallographic direction in a direction of pulling, and pulling a column of the alloy of a length greater than 42 inches from the melt by pulling at a predetermined pulling rate to form a crystallization front above the surface of the melt. Further, claims 20 and 21 of co-pending U.S. Patent Application No. 11/948,852 include steps not present in (nor obvious variations of) claims 16, 17 and 19. For example, claims 20 and 21 of co-pending U.S. Patent Application No. 11/948,852 recite forming a seed of AlCuNi by layering thin layers of aluminum adjacent to layers of copper and layers of nickel, then processing these layers prior to placing the seed into a melt of aluminum, copper and nickel.

For the reasons discussed above, the Applicants assert that currently pending claims 16, 17 and 19 of the instant application are patentably distinct from claims 20 and 21 of co-pending U.S. Patent Application No. 11/948,852, and respectfully request withdrawal of the nonstatutory obviousness-type double patenting rejection.

CONCLUSION

Applicants respectfully request that the Examiner expedite the prosecution of this patent application to issuance. If the Patent Office determines that an extension of time and/or other relief is required, Applicants petition for any required relief including extension of time, and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-4050**, referencing 10265-722.201. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: 12/8/08

By: [signature]
Richard D. Shoop
Registration No. 45,763

SHAY GLENN LLP
2755 CAMPUS DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE: 650.287.2164
FACSIMILE: 650.212.7562